

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE SELENIOUS ACID LITIGATION

C.A. No. 2: 24-cv-7791-BRM-CLW
(consolidated)

AMERICAN REGENT, INC.

Plaintiff

v.

XIROMED, LLC and XIROMED
PHRAMA ESPAÑA, S.L.

Defendants.

C.A. No. 2:24-cv-7811-BRM-CLW

AMERICAN REGENT, INC.

Plaintiff

v.

XIROMED, LLC and XIROMED
PHRAMA ESPAÑA, S.L.

Defendants.

C.A. No. 2:24-cv-11130-BRM-CLW

CONSENT JUDGMENT

American Regent, Inc. (“ARI”), and Xiromed Pharma España, S.L. and Xiromed, LLC (referred to herein together as “XIROMED”), parties in the above-captioned Actions, specifically in the Actions initiated by Plaintiff, ARI, against XIROMED in Civil Action No. 2:24-7811-BRM-CLW and Civil Action No. 2:24-cv-11130, have resolved this

litigation for good cause and valuable consideration recognized by ARI and XIROMED. Now the parties, by their respective undersigned attorneys, hereby stipulate and consent to entry of judgment and an injunction in the Actions, as follows:

IT IS this ____ day of _____, 2025:

ORDERED, ADJUDGED AND DECREED as follows:

1. This District Court has jurisdiction over the subject matter of the above Actions and has personal jurisdiction over the parties.

2. As used in this Consent Judgment, (i) the term “XIROMED Product(s)” shall mean the drug product(s) manufactured, sold, offered for sale or distributed pursuant to Abbreviated New Drug Application No. 219476 (including any supplements, or modification or amendments thereto or replacements thereof) (“XIROMED’s ANDA”); (ii) the term “Licensed ARI Patents” shall mean United States Patent No. 11,998,565 (“the ’565 patent”) and United States Patent No. 12,150,957 (“the ’957 patent”); and (iii) the term “Affiliate” shall mean any entity or person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with XIROMED; for purposes of this definition, “control” means: (a) ownership, directly or through one or more intermediaries, of: (1) more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or (2) more than fifty percent (50%) of the equity interests in the case of any other type of legal entity or status as a general partner in any partnership; or (b) any other arrangement whereby an entity or person has the right to elect a majority of the Board of Directors or equivalent governing body of a corporation or other entity or the right to direct the management and policies of a corporation or other entity.

3. Unless otherwise specifically authorized by ARI pursuant to the Settlement Agreement or by 35 U.S.C. § 271(e)(1), XIROMED, including any of its Affiliates, successors and assigns, is enjoined from infringing the Licensed ARI Patents, on its own part or through any Affiliate, by making, having made, using, selling, offering to sell, importing or distributing of the XIROMED Product(s) in the United States.

4. Compliance with this Consent Judgment may be enforced by ARI, its successors in interest, or assigns, as permitted by the terms of the Settlement Agreement.

5. This District Court retains jurisdiction to enforce or supervise performance under this Consent Judgment and the Settlement Agreement.

6. All claims, counterclaims, affirmative defenses and demands in this Actions are hereby dismissed without prejudice and without costs, disbursements or attorneys' fees to any party. Each party shall bear its own costs, expenses, and attorneys' fees incurred in connection with the claims dismissed by this Consent Judgment.

7. Nothing herein shall preclude the U.S. Food & Drug Administration from granting final approval to XIROMED's ANDA or shall preclude XIROMED from filing, modifying, or maintaining with the FDA any Paragraph IV Certification for the XIROMED Product(s) pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Brian R. Martinotti
United States District Judge

We hereby consent to the form and entry of this Order:

s/ Charles H. Chevalier

Charles H. Chevalier
GIBBONS P.C.
One Gateway Center

s/ Jonathan A. Harris

John C. Leddy
NUTTER, McCLENNEN & FISH LLP
655 Third Avenue

Newark, New Jersey 07102-5310
(973) 596-4611
cchevailer@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

OF COUNSEL

Dennies Varughese, Pharm. D.
Uma N. Everett
Adam C. LaRock
Christina E. Dashe
Alexander Alfano
Ryan E. Conkin
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1101 K Street NW, 10th Floor
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
cdashe@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

*Attorneys for Plaintiff
American Regent, Inc.*

New York, New York 10017
Tel. (646) 440-8000
jleddy@nutter.com

Jonathan A. Harris
Micah W. Miller
155 Seaport Blvd.
Boston, Massachusetts 02110
Tel. (617) 439-2000
jaharris@nutter.com
mmiller@nutter.com

*Attorneys for Defendants Xiromed LLC and
Xiromed Pharma España, S.L.*